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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,790	06/20/2003	Richard Joseph Fagan	674575-2003	8260
20999 7590 06/27/2007 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER HISSONG, BRUCE D	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/600,790

Applicant(s)

FAGAN ET AL.

Examiner

Bruce D. Hissong, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-8 and 51-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-8 and 51-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/18/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

1. The Applicants' response to the office action mailed on 10/18/2006, including arguments/remarks and amendments to the claims and specification, was received on 4/18/2007 and has been entered into the record.

2. Claims 1, 6-8, and 51-62 are currently pending and are the subject of this office action.

Petition to amend inventorship under 37 C.F.R. 1.48(b)(1)

In view of the papers filed 4/18/2007, the inventorship in this non-provisional application has been changed by the deletion of Ursula Boschert and Yolanda Chvatchko.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Information Disclosure Statement

The information disclosure statement received on 4/18/2007 has been fully considered by the Examiner.

Specification

Objection to the specification, regarding embedded hyperlinks, designation of trademarks, and minor typographical errors (TNF□ and IFN□), as set forth on pages 2-3 of the office action mailed on 10/18/2006, is withdrawn in response to Applicants' amendments to the specification to remove the hyperlinks, properly designate trademarks, and correct said minor typographical errors.

Claim Objections

1. Objection to claim 1, as set forth on page 3 of the office action mailed on 10/18/2006, is withdrawn in response to Applicants' amendments to the claim to recite "An isolated polypeptide that.....".

2. Objection to the phrase "four helical bundle cytokine fold", as set forth on page 3 of the office action mailed on 10/18/2006, is withdrawn in response to Applicants' amendments to delete this phrase from the claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Rejection of claims 1 and 6-8 under 35 USC § 101, as being directed to non-statutory subject matter, as set forth on page 3 of the office action mailed on 10/18/2006, is withdrawn in response to Applicants' to the claims to recite "An isolated polypeptide.....".

Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 6-8 remain rejected, and new claims 51-62 are also rejected, under 35 USC § 112, first paragraph, regarding lack of enablement for fragments, "functional equivalents", or polypeptides having only 90% identity to the polypeptide of SEQ ID NO: 2, as set forth on pages 3-5 of the office action mailed on 10/18/2006.

In the response received on 4/18/2007, the Applicants argue that the "functional equivalent", "homologous", and "having an antigenic determinant in common" language has been deleted from the claims, which have also been amended to recite functional language and a high level (at least 90%) of sequence similarity for the claimed polypeptides. The Applicant's

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also assert that the teachings of Mickle *et al*, as set forth in the previous office action, are not applicable to the instant invention because Mickle *et al* describes a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) protein, whereas the instant invention is drawn to an interferon (IFN)- γ like protein. Furthermore, because the IFN- γ family is well-known in the art, a person of ordinary skill in the art would be able to make and use fragments and variants of SEQ ID NO: 2 using simple lab techniques, and therefore the specification is enabling for the full breadth of the claims.

These arguments have been fully considered and are not persuasive. The Applicants' amendments to the claims to recite functional language, while removing phrases such as "functional equivalents", "homologous", and "having an antigenic determinant in common", is noted. However, as currently amended the breadth of the claims is still excessive because the claims recite, or depend from claims which recite, polypeptides having only 90% identity to SEQ ID NO: 2, or fragments thereof, and are thus potentially drawn to a large number of polypeptides or fragments. The specification teaches that the polypeptide of the instant invention is a member of the well-characterized IFN- γ family of proteins, and provides guidance and examples showing that the polypeptide of SEQ ID NO: 2 has biological activity similar to IFN- γ , but provides no examples or guidance showing any polypeptide with only 90% identity to SEQ ID NO: 2, or fragments thereof, that has the claimed biological activities. Thus, the breadth of the claims is excessive in light of the teachings of the specification.

Regarding the teachings of Mickle *et al*, it is noted that Mickle *et al* is silent regarding IFN- γ polypeptides. However, Mickle *et al* underscores the difficulty in predicting the effect of mutations on the function of a given protein. Thus, while the effects of some mutations are known to those skilled in the art, mutations of other residues may or may not be as predictable. Even if the family of IFN- γ proteins is well-known, the polypeptide of the instant invention is not IFN- γ , but rather an "IFN- γ -like" protein with a different primary amino acid sequence. One of ordinary skill in the art would not necessarily be able to predict the effect of mutating all possible amino acid residues required to create a protein with 90% identity to the sequence of SEQ ID NO: 2, and would require further, undue experimentation in order to do so. Therefore, the specification, while being enabling for an isolated comprising comprising or consisting of the amino acid sequence of SEQ ID NO: 2, is not enabling for the full breadth of the claims regarding polypeptides with only 90% identity to SEQ ID NO: 2, or fragments of polypeptides having only 90% identity to SEQ ID NO: 2.

Claim Rejections - 35 USC § 112, first paragraph – written description

Claims 1 and 6-8 remain rejected, and new claims 51-62 are also rejected, under 35 USC § 112, first paragraph, regarding lack of written description for fragments, "functional equivalents", or polypeptides having only 90% identity to the polypeptide of SEQ ID NO: 2, as set forth on pages 5-6 of the office action mailed on 10/18/2006.

In the response received on 4/18/2007, the Applicants argue that the claims have been amended to recite functional language for the polypeptide of SEQ ID NO: 2. The Applicants further assert that the IFN- γ family of proteins was well-known in the art at the time of invention, and variants and muteins of IFN- γ were well-known at that time. Thus, a person of ordinary skill in the art would have had the knowledge to determine which regions or residues of an IFN- γ protein are necessary to maintain biological function. For these reasons, the Applicants argue that the claimed genus of polypeptides or fragments thereof has been adequately described.

These arguments have been fully considered and are not persuasive. As currently amended, the claims recite, or depend from those which recite, polypeptides having only 90% identity to the sequence of SEQ ID NO: 2, or fragments thereof. While IFN- γ is well-known in the art, the instantly claimed polypeptide is not actually IFN- γ , but rather a protein which is similar to IFN- γ in structure and function. The specification has not described all possible polypeptides having only 90% identity to the protein of SEQ ID NO: 2, or described any fragment of a polypeptide having only 90% identity to SEQ ID NO: 2. There is no structure/function correlation for polypeptides having only 90% identity to SEQ ID NO: 2, or for any fragment of such a polypeptide. Accordingly, the genus of polypeptides having only 90% identity to SEQ ID NO: 2, or fragments thereof, has not been adequately described.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Rejection of claims 1 and 6-8 under 35 USC § 112, second paragraph, as being indefinite regarding the term "functional equivalent", as set forth on pages 6-7 of the office action

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mailed on 10/18/2006, is withdrawn in response to Applicants' deletion of the term from the claims.

2. Rejection of claims 1 and 6-8 under 35 USC § 112, second paragraph, as being indefinite regarding the term "IFN- γ -like", as set forth on page 7 of the office action mailed on 10/18/2006, is withdrawn in response to Applicants' deletion of the term from the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

1. Rejection of claims 1 and 6-8 under 35 USC § 102(e) as being anticipated by Penn *et al* (US 2002/0048763 A1), as set forth on page 8 of the office action mailed on 10/18/2006, is withdrawn in response to Applicants' amendments to the claims to recite functional language requiring the polypeptides or fragments of the instant invention to possess anti-viral activity, antiproliferative activity, the ability to increase levels of TNF- α , IL-2, IL-4, IFN- γ , ASAT, or ALAT in vivo, or the ability to induce IFN- γ secretion by concanavalin A or phytohemagglutinin stimulated peripheral blood mononuclear cells. In the response received on 4/18/2007, the Applicants argue that the peptides/polypeptides taught by Penn *et al* do not have IFN- γ -like activity, and thus do not meet the limitations of the instant claims.

These arguments have been fully considered and are persuasive in view of the fact that it would be difficult to build a *prima facie* case that the fragments of Penn *et al* do in fact possess IFN- γ -like activity.

2. Rejection of claims 1 and 6-8 under 35 USC § 102(e) as being anticipated by Drmanac *et al* (US 2002/0048763 A1), as set forth on pages 8-9 of the office action mailed on

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10/18/2006, is withdrawn in response to Applicants' amendments to the claims to recite functional language requiring the polypeptides or fragments of the instant invention to possess anti-viral activity, antiproliferative activity, the ability to increase levels of TNF- α , IL-2, IL-4, IFN- γ , ASAT, or ALAT in vivo, or the ability to induce IFN- γ secretion by concanavalin A or phytohemagglutinin stimulated peripheral blood mononuclear cells. In the response received on 4/18/2007, the Applicants argue that the peptides/polypeptides taught by Drmanac *et al* do not have IFN- γ -like activity, and thus do not meet the limitations of the instant claims.

These arguments have been fully considered and are persuasive in view of the fact that it would be difficult to build a prima facie case that the fragments of Drmanac *et al* do in fact possess IFN- γ -like activity.

3. Rejection of claims 1 and 6-8 under 35 USC § 102(f), regarding whether or not inventors Boschert and Chvatchko invented the claimed subject matter, as set forth on page 9 of the office action mailed on 10/18/2006, is withdrawn in response to Applicants' amendment and petition to delete Ursula Boschert and Yolanda Chvatchko as inventors of the instant application

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Rejection of claims 1 and 6-8 under 35 USC § 101, as claiming the same invention as that of claims 1-10 of copending application 10/872,859, as set forth on page 10 of the office action mailed on 10/18/2006, is withdrawn in view of Applicants' cancellation of claims 1-10 of the '850 application.

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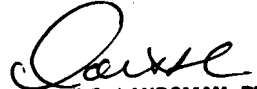
Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
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ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER